Redesign of a Spinal Cord Stimulator Charging System for Patient with Chronic Pain

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Motivation

A spinal cord stimulator (SCS) is a medical implant designed to alleviate chronic pain by sending electrical impulses to the spinal cord. These medical devices consist of three main components: an implant, a generator, and a battery pack, as seen in *Figure 1*. The implant is located on the lower back and contains electrodes that send signals to the spinal cord that block pain signals from reaching the brain. The generator is what transfers a charge to the implant and must be used frequently to recharge the implanted device. The battery pack is what maintains a charge for the generator, and most also be recharged frequently.

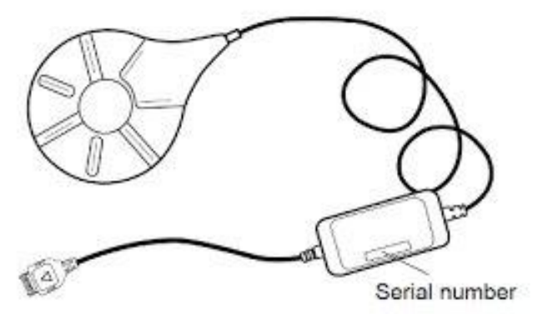


Figure 1: SCS Charger [1]

ELECTRODES

GENERATOR

BATTERY

Our customer Nishka "Nikki" Frank (*Figure 2*) has faced some issues using her SCS device. Her biggest struggle is the recharging system which offers limited feedback while charging, making it difficult to tell when charging is required. The current method of charging requires the customer to remain extremely still, or the charging connection will be lost. Due to Nikki's active lifestyle, the current charging system is inconvenient and hinders her independence every time she must charge her implant.

Figure 2: Nishka Frank, Our Customer

Customer Expectation

The project aims to achieve several key objectives related to enhancing the functionality and usability of spinal cord stimulator chargers. The focus is on developing an improved and more efficient method for maintaining the connection between the internal device and the charging system. Additionally, the project seeks to address the issue of patient forgetfulness by incorporating an active feedback system that aids in user engagement. The design will also introduce an alternative charging mechanism, allowing the device to be charged even when the user is not near a traditional power outlet.

- Emergency on the Go Charging
- Drop Resistant
- Multi-Use Adhesive
- Reminder After Lack of Charging
- USB Charging Capabilities

Requirement / Constraint	Significance
Secure charging connection	Essential
Mobile (on-the-go) charging	Essential
Battery alert	Critical
Alert for initiated charging	Critical
Charging reminder	Important
Completed charging alert	Important
Lightweight and compact	Important
Durability	Important
Aesthetic	Desirable

Design Concepts

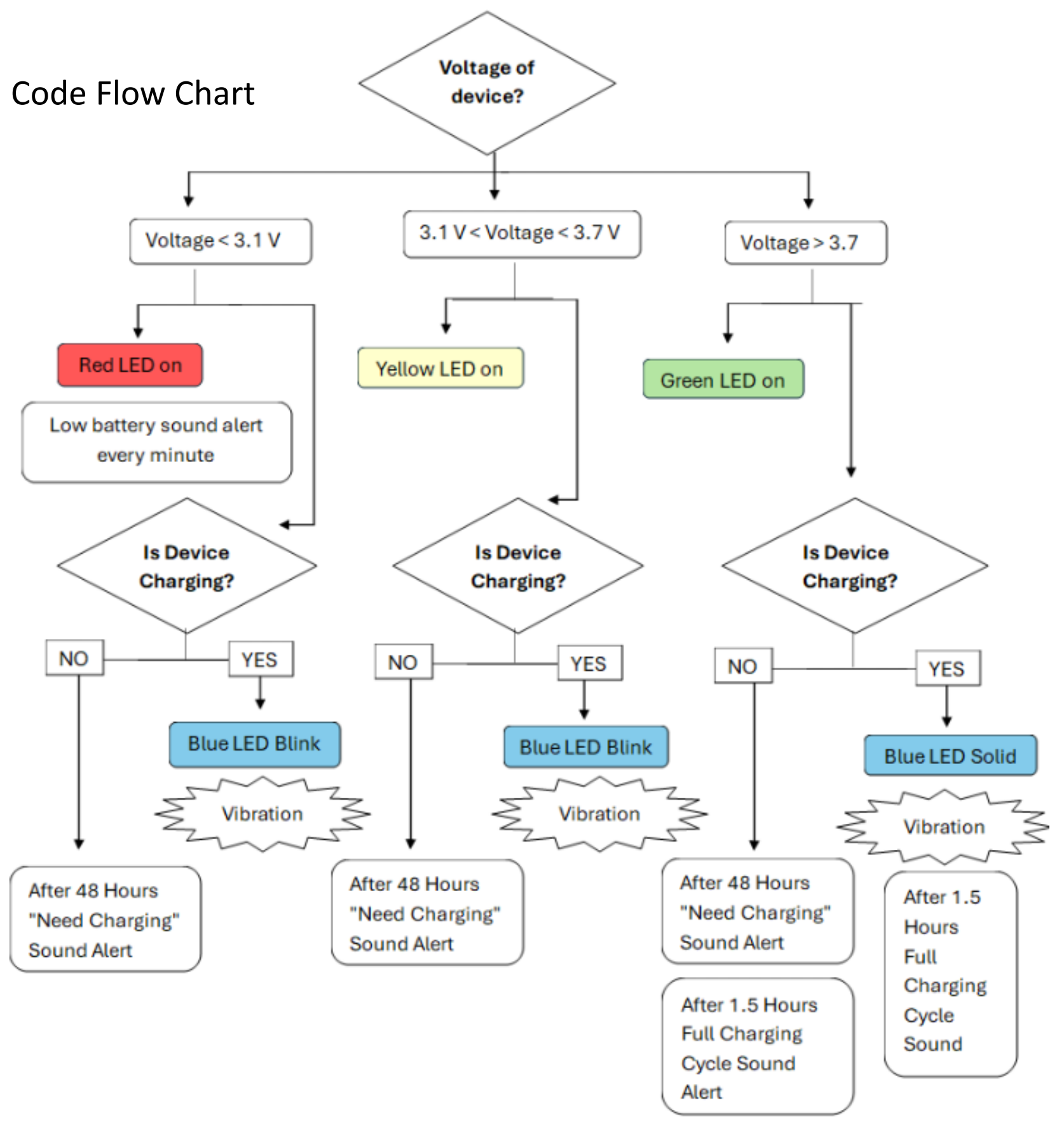
Kinetic Hand Crank

The implementation of the kinetic charging component within this project serves the fundamental purpose of providing our customer with a reliable means of replenishing their device's power reserves while on the move, thereby ensuring uninterrupted connectivity and functionality.

Electronics

Due to the patient's need to for active feedback while charging, visuals, sounds, and vibrations were incorporated into the circuit. Arduino software was used to develop code following the logic found in *Figure 3*.

Figure 3: Code Flow Chart



The first circuit was developed using an Arduino UNO board which was switched to an Arduino Nano Every board in later iterations due to sizing restraints. The circuit diagram in *Figure 4* depicts the final design, which was created using KiCad software [2]. The final design was a soldered PERF board.

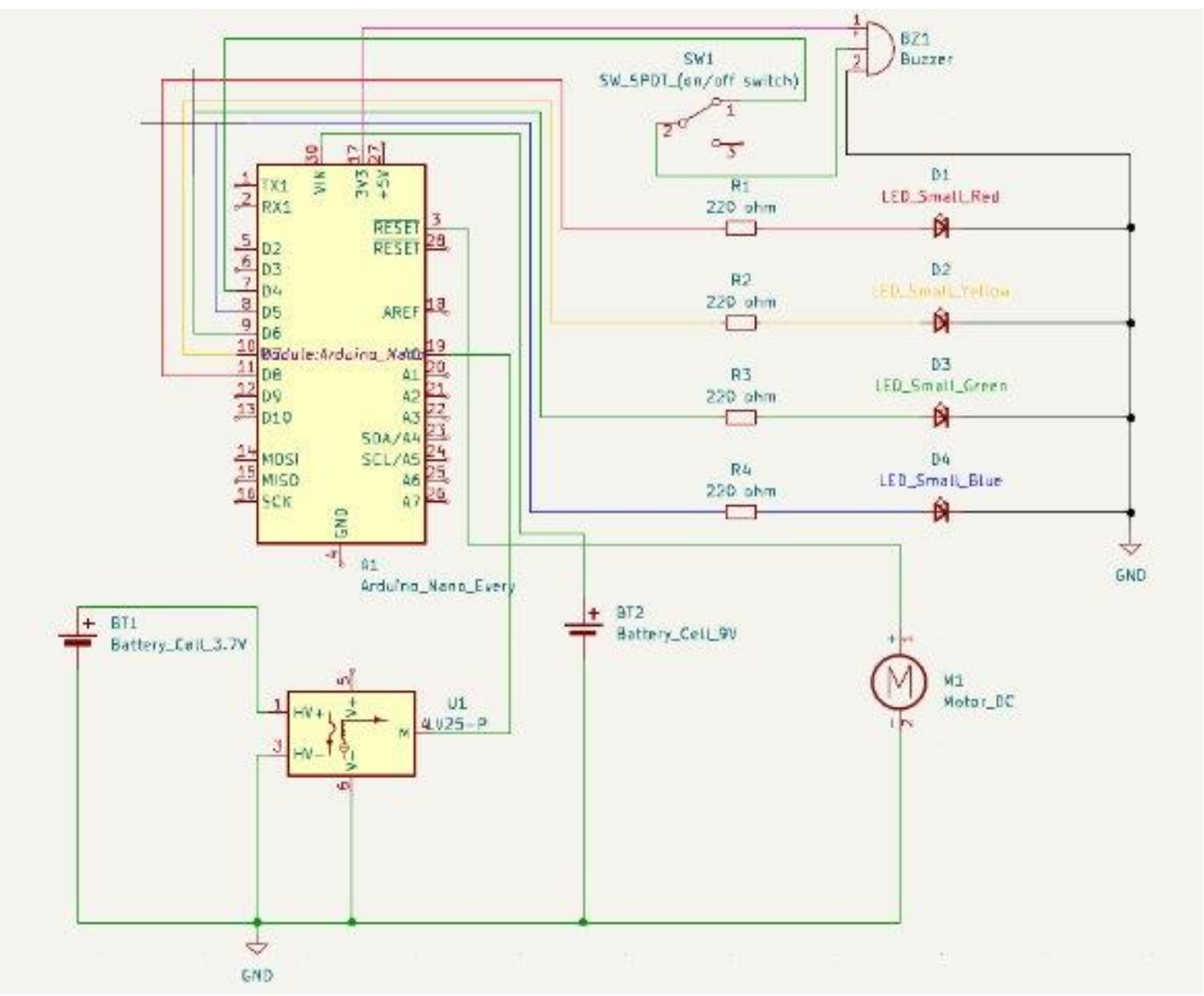


Figure 4: Final Circuit Diagram

Modeling

Battery: SolidWorks was used to design a PLA case to encompass the kinetic crank and electronics. It was a two-part design with a compartment which opened on one side to provide easy access to replace the 9V battery. To prevent damage during potential drops, Elastico was placed on the corners of the battery.

Generator: ImageJ software was used to analyze the dimensions of the current device based on a scaling factor associated with a quarter for reference [3]. SolidWorks was then used to CAD a model approximately the size of the current device. An additional TPU backing flap was positioned to encompass the circuitry of the wireless charger.

Adhesive

Incorporation of an adhesive was crucial in the final design to increase independence and activity for our customer during charging sessions. A multi-use adhesive allows our product to stand out among competitors and reduce waste.

Testing

Kinetic Charging Testing

The objective of this test was to measure and compare the voltage and current in the kinetic hand crank and USB charger, both before and after assembly, to ensure consistency. A multimeter was used to gather average voltage and current data throughout testing. The hand crank operated at approximately 25 cranks per minute.
Hand Crank: ~ 1 hour and 30 minutes to fully charge.
USB Charging Cable: ~ 30 minutes to fully charge.

Wireless Charging Testing

Used to determine the functional charging distance of the wireless charger based on Medtronic consultant feedback. Sticky notes were used to increase the distance between the wireless charger and responding device until the device no longer responded. The functional charging distance was found to be 0.2576 in or 0.65 cm. This test inspired design changes to the generator regarding adhesive and wireless charger placement

Circuitry Testing

Audibility: Performed to ensure that the alerts can be heard in the customers everyday environment. The average and maximum decibels of each sound were found by averaging five trials of each sound using the app DecibelX. The sound was deemed acceptable if over 60 dB and desirable if between 70-80 dB. Every sound was observed to be audible for its intended application.

Visibility: To ensure LEDs can be seen in the customers everyday environment. Two environments were tested, light and dark. All LEDs were found to be visible.

Correctness: Utilized to verify the safety and effectiveness of the device to react properly to specific stimuli. Six states were tested low, medium, and high battery at both charging and not charging states. All components responded correctly in every scenario except one, there was a missing vibration when at low battery and charging; however, due to simultaneous alerts and no false data being conveyed the device was considered acceptable.

Drop Resistance Testing

To verify the safety of internal components in the battery case during falls. The case was dropped from one meter in three different orientations, with each orientation being tested three times. The component safety was evaluated by testing the Arduino's functionality before and after drops as well as inspecting the device for any damage. The results showed no damage, confirming the case's protection.

Temperature Testing

The test aimed to ensure that the generator did not exceed 75°C to prevent burns during charging. The wireless charger was activated for three hours during which temperature measurements were taken hourly. The results confirmed that the temperatures remained below the threshold, indicating no risk of burns for the customer.

Adhesive Testing

Preface: An IRB (2158014-1) was secured for testing adhesive on human subjects and participants were required to complete consent forms.

Lifetime: Two adhesive brands were tested under static conditions on faux skin to determine which possessed more desirable qualities. Tens Unit pads proved successful and were tested under dynamic conditions on real skin. Lifetime testing demonstrated that our adhesive withstands a charging time of at least 3 hours for up to 7 uses. This correlates to 1-2 weeks of use.

Irritation: While the adhesive used was already recognized as biocompatible, irritation testing was completed to ensure minimal irritation risks to our customer. Before and after pictures of each trial were taken and analyzed with ImageJ software according to standard ISO 10993-23:2001 [4]. Overall, our adhesive does not pose a significant irritation risk.

Recommendations/ Future Directions

For further enhancements of our design, we recommend the following improvements. First, gaining access to an actual SCS and its charging system would allow for a design that better aligns with our customers current model. This could facilitate the development of features more compatible with existing devices. Secondly, user interface improvements are suggested; specifically, replacing musical cues with spoken words or commands could provide users with clearer and more direct information regarding battery life and charging status. Lastly, integrating the kinetic charging system directly into the main PCB could significantly reduce the overall size of the battery pack, making the device more compact and user-friendly. There recommendations aim to refine functionality and enhance user experience.

Figure 5: Finalized Product

Conclusion

Our SCS charging device underwent multiple iterations to meet customer needs and engineering specifications, featuring visual, audio, and vibrational feedback with USB and kinetic crank charging options. The device uses an adhesive that supports the generator for three hours and lasts seven uses, replacing the current belt design. Drop tests confirmed that the protective casing adequately protects the device. Due to FDA regulations, our prototype serves as a proof of concept rather than a commercial product. This successful project paves the way for future development by senior design teams and potential commercialization by SCS manufacturers.

References

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Acknowledgements

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